510(k) Summary: K123005

DEC 7 2012

1. Submitter:
Swissray Medical AG
Turbistrasse 25 – 27
CH-6280 Hochdorf
Switzerland
Phone +41 41 914 12 12
Fax +41 41 914 12 13
Date Prepared: November 13, 2012
Contact: Markus Bütler, Quality Manager

2. Identification of the Device: ddRVersa™ Motion (Digital Diagnostic X-Ray System);
Recommended classification regulation: 21 CFR 892.1650, 892.1680
Device class: II, Panel: Radiology, Product code: MQB and KPR

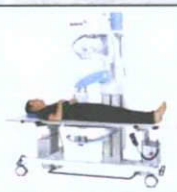
3. Predicate Device: This is a MODIFICATION to ddRElement™ under document number K110828 and Suinsa (Now owned by Sedecal) (K083109).

4. A description of the device: ddRVersa™ Motion uses the same core technology as our ddRElement but is modified in that:
The supplier for the digital x-ray receptor panel has changed.
The system can now accommodate two digital x-ray receptor panels instead of just one.
A Wi-Fi digital x-ray receptor panel may be chosen as the second panel.
The tubestand is changed from a C-arm configuration to an overhead plus wall stand configuration.
The table is changed from non-motorized to motorized.
The generator supplier has been changed.
The collimator has been changed. (See comparison table below)

5. Intended use of the device: Intended for use by a qualified/trained doctor or technician on subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography) (SAME as predicate)

6. The ddRVersa™ Motion has essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device ddRElement™. See the comparison table below. There are really only two main differences: The tubehead is now an overhead version and the system can now accommodate two digital panels. The panel resolution and technology remains the same.

Comparison Table

Characteristic	Suinsa (Now owned by Sedecal) (K083109)	Swissray ddRElement™ (K110828)	Swissray ddRVersa™ Motion (K123005) (New modified device)
Overall Configuration			

Characteristic	Suinsa (Now owned by Sedecal) (K083109)	Swissray ddRElement™ (K110828)	Swissray ddRVersa™ Motion (K123005) (New modified device)
Intended Use	General purpose radiography except not for mammography	SAME	SAME
Control System: Positioning	Software Driven with Touch Panel LCD (Sedecal product)	Manual	Software Driven via Windows workstation with touch-screen monitor, keyboard, and mouse
Control System: Exposure	Software Driven with Touch Panel LCD (Sedecal product)	Software Driven via Windows workstation with touch-screen monitor, keyboard, and mouse (Samsung LTX240AA01-A, K090742)	Software Driven via Windows workstation with touch-screen monitor, keyboard, and mouse (Pixium 4343 RC or Portable 3543 EZ)
Configuration: Tube	Ceiling-mounted single tube; automatic positioning (utilizing Sedecal Nova FA X-Ray tube overhead support system)	Single tube column-mounted on U-Arm with detector; manual positioning	SAME AS SEDECAL Ceiling-mounted single tube; automatic positioning (utilizing Sedecal Nova FA X-Ray tube overhead support system)
Configuration: Detector/Image Receptor	Not applicable	One detector system: Column-mounted U-Arm with tube with Samsung LTX240AA01-A panel (K090742)	Two detector system: Wall-mounted (column) and Table-mounted
Receptor Details	Not applicable	Technology Single A-Si TFT + photodiode plate Cesium iodide scintillator (CsI) A/D conversion 14 bit Active detector area 43 cm x 43 cm Spatial resolution 3.0 lp/mm Active pixel matrix 3072 x 3072 pixels Pixel size 143 µm Energy range 40-150 kVp Sensitivity > 120 LSB/µGy	Technology Single A-Si TFT + photodiode plate Cesium iodide scintillator (CsI) A/D conversion 16 bit Active detector area 43 cm x 43 cm Spatial resolution 3.5 lp/mm Active pixel matrix Active pixel matrix 2880 x 2880 pixels Pixel size 148 µm Energy range 40- 150 kVp Sensitivity up to 850 LSB/µGy
Generator: Type	High frequency made by Sedecal	CPI Canada CMP200 high frequency generator	High Frequency SHF 635/645 or SHF 835/845 made by Sedecal
Generator: Capacity	30 kW to 64 kW	65 – 80 kW	64kW or 80kW

Characteristic	Suinsa (Now owned by Sedecal) (K083109)	Swissray ddRElement™ (K110828)	Swissray ddRVersa™ Motion (K123005) (New modified device)
Detector/Image Receptor: Resolution	Not applicable	Samsung LTX240AA01-A (K090742)	Trixell 4343 RC a-si TFT flat panel or Pixium Portable 3543 EZ : 148 microns pixel size, with 2880 x 2880 pixels (8.2 mil pixels) 16 bit
Tube: Type	Toshiba 7869x 0.6/1.2	Dunlee DR1436CRSR	Toshiba 7869x 0.6/1.2
Tube: Capacity	150KV	150KV	150KV
Collimator + cu filter	Huestis	Siemens ML02	Ralco 225 43x43cm Motorized filters 1mm AL +0.1mm Cu 1mm AL +0.2mm Cu 2mm AL
Energy Source:	120V, 230/240 V 50/60 Hz	SAME	SAME
Performance Standard	21 CFR 1020.30	SAME	SAME
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2

7. Description of non-clinical tests. The modified unit has undergone electrical safety and electromagnetic compatibility testing, as well as software validation and risk analysis. The technical characteristics of the new panel have been measured and included in the bench testing information.

8. Description of clinical tests. Clinical images were obtained in accordance with the FDA Guidance Document on Solid State Imaging Devices. They were compared to our predicate images and evaluated by professional radiologists and found to be of good diagnostic quality.

9. Conclusions drawn: The nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Swissray Medical AG
% Mr. Daniel Kamm, P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34113

December 7, 2012

Re: K123005
Trade/Device Name: ddRVersa™ Motion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 16, 2012
Received: November 20, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123005

Device Name: *ddRVersa™ Motion*

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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